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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,870	06/23/2000	John D Brennan	086671/0109	1416

22428 7590 06/14/2005

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EXAMINER	
DO, PENSEE T	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/599,870	BRENNAN ET AL.	
	Examiner	Art Unit	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry and Claim Status

The amendment filed on March 4, 2005 has been acknowledged and entered.

Claims 50-65 are pending.

Rejection(s) Withdrawn

Rejection under 112, 2nd paragraph in the previous office action is withdrawn herein.

Rejections under 102(e) in the previous office action are withdrawn herein.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 50-52, 54-56, 61-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Gray et al. (Journal of Immunological Methods 182 (1995) pp.155-163).

Gray teaches a method of using agarose microdroplets to encapsulate cells that secrete its antibody. The agarose matrix is covalently modified with biotin. After cell encapsulation, avidin is added in excess to create a bridge to bind biotinylated capture reagents, either goat anti-mouse antibody or antigen that would bind to the secreted antibody from the cell. Fluorescent complementary reporter agent, either antibody or antigen, is also added to label the bound secreted antibody. (see p. 155-156; figure 1).

Since the biological species in Gray are proteins, i.e. antigen and antibody, and same as the biological species being claimed by the present invention, these biological species are inherently capable of being reversely disrupted under reversibly disrupting conditions. Regarding claims 51, 52, and 56, since the matrix of Gray is the same as the matrix of the present invention, made up of organic material, it inherently inhibits aggregation of the biological species under denaturing conditions and also inherently has pore size to inhibit leaching out of the biomolecular interaction or biological species thereof. For claim 54, the biological species of the biomolecular interaction can under naturing conditions associate with one another. For claim 61, the biomolecular interaction is bioactive. Regarding claims 60, 62-65, because the limitations of these claims are drawn to a process of use or a process of making, they are not given any patentable weight. Regarding claim 55, since the biological entities of Gray are the same as those of the present invention and they interact, they inherently interact/associate by either ionic bonds, hydrogen bonds, van der Waal's interactions, hydrophobic interactions, dipole-dipole interaction, etc.

Claims 50-52, 54-56, 61-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Weaver et al. (US 4,959,301).

Weaver teaches a gel microdroplet (GMD). GMDs are very small volume entities which comprise at least one gel region, and which provides a mechanical matrix capable of entrapping biological entities such as antibodies, antigens etc. The GMDS can consist entirely of gel, which case containment of biological entities. Macroscopic gel are gel slabs, Petri dishes, and gel beads. (see col. 7, lines 54-67). The term gel

refers to a porous matrix with high water content. Structures have the ability to entrap biological entities while allowing transport of many molecules within the aqueous solution with inorganic and/or organic chemical compounds. Natural gels are agarose, collagen, fibrin, etc. (see col. 8, lines 47-67).The GMDs are also provided with binding sites for capture molecules within the GMDs. The process of capturing molecules consist of: incorporating specific sites and biological entities into GMDs, allowing molecules released from biological entities in GMDs to move by diffusion, convection or drift within the GMDs, such that some molecules encounter the binding sites and are bound at such sites, thereby capturing molecules released from biological entities at binding sites within GMDs. (see col. 29, lines 40-64). Microdroplets are also incubated for biochemical and biological interactions to occur. Incubation includes biochemical reactions and processes relating to replication of genetic material, ligand binding, aggregation based on specific binding such as occurs in antibody-antigen reactions, etc. (see col. 28, lines 40-51). The term biological entity refers to small biological structures which capable of being incorporated into liquid microdroplets and/or gel microdroplets, and includes cells, viruses, nucleic acid molecules, antibody molecules, antigen molecules, etc. (see col. 28, lines 61-67). Since the biological species in Weaver are proteins, i.e. antigen and antibody, and same as the biological species being claimed by the present invention, these biological species are inherently capable of being reversely disrupted under reversibly disrupting conditions. Regarding claims 51, 52, and 56, since the matrix of Weaver is the same as the matrix of the present invention, made up of organic material, it inherently inhibits aggregation of the biological species under

denaturing conditions and also inherently has pore size to inhibit leaching out of the biomolecular interaction or biological species thereof. For claim 54, the biological species of the biomolecular interaction can under naturing conditions associate with one another. For claim 61, the biomolecular interaction is bioactive. Regarding claims 60, 62-65, because the limitations of these claims are drawn to a process of use or a process of making, they are not given any patentable weight. Regarding claim 55, since the biological entities of Weaver are the same as those of the present invention and they interact, they inherently interact/associate by either ionic bonds, hydrogen bonds, van der Waal's interactions, hydrophobic interactions, dipole-dipole interaction, etc.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 50-65 are rejected under 35 U.S.C. 102(e) as being anticipated by Charych et al. (US 6,022,748).

Charych teaches a method and composition for direct detection of analytes using color changes that occur in immobilized biopolymeric material in response to selective binding of analytes to their surface. The composition relates to the encapsulation of biopolymeric material into metal oxide glass using sol-gel method. The biopolymeric material comprise of self-assembling monomers and consist of liposomes, films, multilayers, tubular, helical, fiber-like shapes, solvated coils. (see col. 3, lines 5-8). These biopolymeric materials also comprises a ligand such as peptide, antibody, antigen, nucleic acid, biotin, etc. (see col. 3, lines 30-40). The polymeric material is

encapsulated in sol-gel glass. In operation, the sol-gel glass encapsulating the biopolymeric material with the ligand is exposed to the analytes to allow interaction of the ligand with the analytes. (see col. 14, lines 21-42). The pore size of gel likely provided a level of selectivity in these sensor materials, screening out larger interferants, such as bacterial cells (micron size), while allowing selective permeation of smaller agents, such as viruses. It is contemplated that by altering the gelling conditions, the pore sizes can be controlled to optimally allow interaction of a given ligand with a variety of differently sized analytes with controllable response times. (see col. 21, lines 50-62). Since the biological species in Charych are proteins, i.e. antigen and antibody, and same as the biological species being claimed by the present invention, these biological species are inherently capable of being reversely disrupted under reversibly disrupting conditions. Regarding claims 53 and 57, it is inherent that the pore size of the carrier is selected to enable potential modulators of the biomolecular interaction to pass in and out of the matrix since Charych teaches that the pore size of the carrier is adjustable accordingly to the allow small molecules or analytes to pass in and out of the carrier. Regarding claim 58-60, Charych teaches that the porous metal oxide matrix is derived by a sol-gel. The sol-gel glass is silica base glass. (see col. 17, lines 31-55). The inorganic material is selected from the group consisting of metal oxides such as silicates, titanates, aluminates which read on silicate precursors, functionalized metal oxides of the present invention (see col. 17, lines 60-62). Regarding claims 51, 52, and 56, since the matrix of Charych is the same as the matrix of the present invention, made up of organic material, it inherently inhibits

aggregation of the biological species under denaturing conditions and also inherently has pore size to inhibit leaching out of the biomolecular interaction or biological species thereof. For claim 54, the biological species of the biomolecular interaction can under naturing conditions associate with one another. For claim 61, the biomolecular interaction is bioactive. Regarding claims 60, 62-65, because the limitations of these claims are drawn to a process of use or a process of making, they are not given any patentable weight. Regarding claim 55, since the biological entities of Charych are the same as those of the present invention and they interact, they inherently interact/associate by either ionic bonds, hydrogen bonds, van der Waal's interactions, hydrophobic interactions, dipole-dipole interaction, etc.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
June 9, 2005

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06/10/05